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Provisional MRL and uniform tolerance

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Report Highlights:
The report highlights proposed procedures from Japan's MHLW for the establishment of 1) provisional maximum residue limits (MRLs), 2) MRLs for processed foods, and 3) a uniform tolerance, that are a part of introduction of a positive list system; a system to prohibit the distribution of foods that contain agricultural chemicals above a certain level of MRLs.

Includes PSD Changes: No
Includes Trade Matrix: No
Unscheduled Report
Tokyo [JA1]
[JA]

On May 26, 2004, the Pesticides and Veterinary Subcommittee of the Food Sanitation Committee of the Ministry of Health, Labor and Welfare (MHLW) met and explained proposed procedures as part of the positive list system for the establishment of 1) provisional maximum residue limits (MRLs), 2) MRLs for processed foods, and 3) a uniform tolerance. The positive list system is outlined in previous GAIN reports JA2074 and JA3071. Until a full risk assessment is completed on all MRLs, MHLW will introduce provisional MRLs based on currently available information; domestic residue standards, Codex MRLs, and MRLs of foreign countries that determine them based on sound science. The provisional MRLs will be finalized by May 2006 when the positive system will be fully implemented.

The explanation was made as a response to public comments on the positive list system and the first draft of provisional MRLs (see JA3071). Those responses to the comments discussed at the May 26 meeting were in draft form and will be finalized later. Requests to change the standards appearing in the first draft of provisional MRLs may be submitted using the request form and appropriate documentation. A uniform tolerance at 0.01 ppm was unofficially proposed at the meeting, but a food safety evaluation of the uniform tolerance will be submitted to the Food Safety Commission at a later date.

Informal translation of highlighted points of MHLW text:

Procedure for Provisional MRL Establishment

From the point of view of public health protection and prevention of unnecessary trade barriers, provisional MRLs are established using the following procedure.

1. Refer to Codex standards, withholding limits, and foreign countries' limits established by scientific methods equivalent to that used by JMPR.

2. Considering that Japan is a member of WTO Treaty, it is MHLW's basic position to adopt Codex standards whenever possible.

3. For those cases without Codex standards, standards established in Japan, such as withholding limits (WHLs) for pesticides, will be adopted. (The limits have been used for registration of pesticides by Ministry of Environment and Ministry of Agriculture, Forestry and Fisheries and are regarded to be scientifically based on toxicology and residue test results. In contrast, we have not received such test results for standards from foreign countries. Therefore, it is scientifically appropriate and consistent with international methods of establishing standards, to adopt standards from the Japanese government's MOE and MAFF based on toxicological test results and other scientific evidences.)

4. In the cases where there is neither Codex standards nor domestically established standards, standards in foreign countries are referenced.

5. If multiple countries have different MRLs, the average will be taken. (Each country applies its own standards for both domestic and imported products, and the countries establish standards scientifically based on residue test results, etc. In addition, it is difficult to perform full risk analysis, including establishments of ADI, residue amounts and intake amounts for all pesticides, in time for the positive list introduction.)

6. Codex standards are basically applied on domestic products (as stated in paragraph 2). However, if there is a legitimate reason to apply domestic standards, based on their production, distribution and pesticide use practice, those domestic standards such as WHLs are adopted. Domestic standards are basically applied on imported products (as stated in paragraph 3). However, if there is a need to take into consideration distribution, production

and pesticide use practices, foreign standards are to be adopted. For example, standards for those products with low self-sufficiency ratio as shown on the MAFF website, (grapefruit, lemon, pineapple, wheat and soybean) foreign countries' standards are basically adopted. The information on corn is not available in the MAFF website and it is still under investigation.

7. For veterinary drugs, the basic position is the same. (However, there will be a preference for standards that MAFF has notified based on domestic residue tests.)

8. If there is any desire to change the standards that are in the first draft of the provisional MRLs, it is possible to submit a request using the request form and appropriate documentation.

9. For pesticides mainly used abroad, and desired to be put outside the scope of the positive list, please submit your request using 'Guideline for Application for Establishment and Revision of Maximum Residue Limits for Agricultural Chemicals used outside Japan' (http://www.mhlw.go.jp/english/topics/foodsafety/dl/importguideline.pdf) with necessary documentation.

Processed food

For MRLs of processed foods, a "uniform tolerance" will basically be applied. If a detected residue in a processed food exceeds the uniform tolerance, the judgment as to whether the processed foods may be distributed will be made based on residue standards for individual agricultural products as ingredients. If the decision cannot be made at the point, the ingredients will actually be inspected.

For processed foods that have Codex standards, provisional standards are established by referring to the Codex standards.

Establishment of Uniform tolerance (Draft)

1. For all pesticides used in Japan and foreign countries, scientifically established residue standards will be in place under the positive list system. Therefore, the uniform tolerance is basically applied only on residues of pesticides on agricultural products whose use is not permitted.
2. JECFA and USFDA evaluated the safety of flavorings and indirect food additives respectively. Their conclusions may be commonly applied, from a point of view of safety of the chemicals, to pesticide residues. Based on their conclusions, it is considered to be legitimate to refer to 1.5 ug/day as the threshold for allowed exposure. The allowance level is defined as ensured safety even when a person takes a chemical at this level his whole life.
3. ADI is calculated using a body weight of 50 kg and the threshold level of 1.5 ug/day is 0.03 ug/kg/day. Among 419 ADIs of pesticide and veterinary drugs that Japan, JMPR or JECFA evaluated, only 3 MRLs of veterinary drugs (0.7 % of total) fall below the 0.03 ug/kg/day ADI. Therefore, the level is also considered appropriate from this point of view. For chemicals evaluated to have ADIs lower than 0.03 ug/kg/day, individual detection methods have to be developed and the residues have to be established as "not detected."
4. If a person intakes 150 g of a food with 0.01 ppm pesticide residue, the exposure of the person reaches 1.5 ug/day. However, ADI refers to the safety level if a person eats this amount for his entire life every day. In addition, only rice exceeds the level of intake in the case of the Japanese, and chemical residues in rice are strictly

regulated by the Pesticide Enforcement Law in Japan. Therefore, residue intake from rice is not considered to exceed the ADI of 1.5 ug/day for a person's entire life.

5. Those countries having positive list systems have established uniform tolerances ranging from 0.01 ppm to 0.1 ppm. The EU is also proposing 0.01 ppm as the uniform tolerance.

Based on the above information and the outcome of a scientific research project for the establishment of a uniform tolerance from a safety point of view (expected to be obtained within a year), the Food Safety Commission will then be requested to do a food safety evaluation of the uniform tolerance.